K132234

510(k) SUMMARY

SUBMITTED BY:

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AUG 2 8 2013

DATE PREPARED: July 17, 2013

NAME OF DEVICE:

Trade Name: LIAISON® Toxo IgG II
LIAISON® Control Toxo IgG II

Common Names/Descriptions: Toxoplasma gondii IgG assay and
Toxoplasma gondii IgG controls

Classification Names: Toxoplasma gondii serological reagents:
Class II, 21 CFR: 866.3780; Microbiology (83)

Single (Specified) analyte controls (assayed and unassayed): Class I, reserved
21 CFR 862.1660; Clinical Chemistry (75)

Product Code: LGD
JJX

PREDICATE DEVICES : Diamedix Is-Toxoplasma IgG ELISA
Reference K981498 (assay)
DiaSorin LIAISON® Control Rubella IgM
(K122397)

DEVICE DESCRIPTION:

INTENDED USE:
The LIAISON® Toxo IgG II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the qualitative determination of specific IgG antibodies to *Toxoplasma gondii* in human serum. The results of this assay can be used as an aid in the assessment of the patient's serological status to infection with *Toxoplasma gondii* and in the determination of immune status of individuals including pregnant women

This assay has not been cleared/approved by the FDA for blood/plasma donor screening.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants.

The LIAISON® Control Toxo IgG II (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Toxo IgG II assay on the LIAISON® XL Analyzer.

KIT DESCRIPTION:

The method for qualitative determination of IgG antibodies to *Toxoplasma gondii* (anti-Toxo IgG) is an indirect chemiluminescence immunoassay (CLIA). The principal components of the test are magnetic particles (solid phase) coated with *Toxoplasma gondii* and a conjugate of mouse monoclonal antibodies to human IgG linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, *Toxoplasma gondii* antibodies present in diluted calibrators, samples or controls bind to the solid phase. During the second incubation, the monoclonal antibody conjugate reacts with anti-Toxo IgG that is already bound to the solid phase. After each incubation, unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and therefore, the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of the presence of anti-Toxo IgG in calibrators, samples or controls.

All assay steps and incubations are performed by the LIAISON® XL Analyzer.

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® Toxo IgG II assay is substantially equivalent in principle and performance to the Diamedix Is-Toxoplasma IgG ELISA (K981498) which was FDA cleared August 21, 1998. The DiaSorin LIAISON Control Toxo IgG II is substantially equivalent in principle to the DiaSorin LIAISON Control Rubella IgM (K122397) which was FDA cleared September 6, 2012.

Table 1: Table of Similarities		
Characteristic	**New Device DiaSorin LIAISON® Toxo IgG II**	**Predicate Device Diamedix Is-Toxoplasma IgG ELISA (K981498)**
Intended Use	The LIAISON® Toxo IgG II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the qualitative determination of specific IgG antibodies to *Toxoplasma gondii* in human serum. The results of this assay can be used as an aid in the assessment of the patient's serological status to infection with *Toxoplasma gondii* and in the determination of immune status of individuals including pregnant women. This assay has not been cleared/approved by the FDA for blood/plasma donor screening. U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants.	The Diamedix Is-Toxoplasma IgG Test Kit is an enzyme-linked immunoassay (ELISA) for the qualitative and quantitative detection of IgG to *Toxoplasma gondii* in human serum. The results of the assay can be used as an aid in the assessment of the patient's immunological response to infection with *T. gondii* and in the determination of immune status of individuals, including females of child-bearing age. The evaluation of paired sera can aid in the diagnosis of primary or reactivated infection. This product is not FDA cleared for use in screening blood and plasma donors.
Measured Analyte	IgG antibodies to *Toxoplasma gondii*	Same
Reagent Storage	On-board or in refrigerator @ 2-8°C	In refrigerator @ 2-8°C
Calibrators	Included with kit	Same
Controls	2 levels (negative and positive)	Same
Sample matrix	Human Serum	Same

Table 2 : Table of Differences		
Characteristic	**New Device DiaSorin LIAISON® Toxo IgG II**	**Predicate Device Diamedix Is-Toxoplasma IgG ELISA (K981498)**
Assay Type	Chemiluminescent Immunoassay	Enzyme Immunoassay
Calibration Standarization	E6 (National Health Laboratory, France, 1987) standardized against WHO 2nd International Standard	WHO 3rd International Standard
Calculation of Results	Qualitative assay	Qualitative or Quantitative
Calibration	Two point verification of stored master curve	Single point Cut-Off Calibrator (Qualitative) Three point – 3 Standards
Unit of Measure	IU/mL	Index Value (Qualitative) IU/mL (Quantitative)
Cut-Off	≥ 8.8 IU/mL	1.10 Index Value (Qualitative) 50.0 IU/mL (Quantitative)
Equivocal Zone	≥ 7.2 – < 8.8 IU/mL	0.90 – 1.09 Index Value
Sample size	20 µL	Minimum of 2 µL
Sample Handling/ Processing	Automated	Manual or Automated
Assay Time	35 minutes	140 minutes
Controls	Provided Separately	Included with kit
Conjugate	Mouse monoclonal to human IgG linked to isoluminol derivative	Goat anti-human IgG labeled with horseradish peroxidase
Measurement System	Photomultiplier (flash chemiluminescence reader)	Spectrophotometer (EIA microtiter plate reader)

Table 3: Summary of Similarities and Differences LIAISON® Control Toxo IgG II		
Characteristic	**New Device DiaSorin LIAISON® Control Toxo IgG II**	**Predicate Device DiaSorin LIAISON® Control Rubella IgM (K122397)**
Intended Use	The LIAISON® Control Toxo IgG II is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Toxo IgG II assay.	The LIAISON® Control Rubella IgM is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Rubella IgM assay.
Storage	Store at 2-8° C until ready to use	Same
Levels	2 levels: negative and positive	Same
Open Use	8 weeks stored at 2-8° C	Same
Matrix	Liquid human serum or defibrinated plasma provided in vials 0.2% ProClin® 300	Same

PERFORMANCE DATA:

COMPARATIVE CLINICAL STUDIES:

Prospective and retrospective studies were performed to evaluate the performance of the LIAISON® Toxo IgG II assay among individuals who were sent to the lab for *Toxoplasma gondii* testing, pregnant women (prospective) and on frozen or repository samples from individuals with a positive *Toxoplasma gondii* IgG result by the comparator assay (retrospective).

A. Prospective:

The prospective populations consist of non-selected subjects sent to the laboratory for *Toxoplasma gondii* IgG testing (US and European subjects) and pregnant women.

The prospective US population consisting of 204 individuals were 96.1% Female (n=196) and 3.9% Male (n=8) ranging in age from 18 years to 42 years. There were 147 samples from patients where the age was unknown.

The prospective European population consisted of 600 individuals. Age and gender for these samples are unknown.

The prospective population of pregnant women consists of 202 females with ages ranging from 14 years to 44 years. There were 71 samples from subjects in the 1st trimester, 50 samples form subjects in the second trimester and 81 samples from subjects in the 3rd trimester of pregnancy.

Toxoplasma IgG Prospective US Population Comparison

		Percent Agreement	Exact 95% Confidence Interval
Negative	183/183	100.0%	98.0 – 100.0%
Positive	21/21	100.0%	84.5 – 100.0%

Toxoplasma IgG Prospective European Population Comparison

		Percent Agreement	Exact 95% Confidence Interval
Negative	252/267	94.3 %	90.9 – 96.6%
Positive	329/333	98.8 %	96.6 – 99.5%

Toxoplasma IgG Pregnant Population Comparison

		Percent Agreement	Exact 95% Confidence Interval
Negative	188/188	100.0 %	98.0 – 100.0%
Positive	12/14	85.7 %	60.1 – 96.0%

B. Retrospective/PreSelected Population;

The retrospective population was defined as pre-selected samples from individuals who had a positive *Toxoplasma gondii* IgG result by the comparator assay. Forty two (42) samples were included in this study. The 42 individuals from the retrospective population were 95.2% females (n=40) and 4.8% males (n=2) ranging in age from 0 to 47 years.

Toxoplasma IgG Retrospective Population

		Percent Agreement	Exact 95% Confidence Interval
Positive	42/42	100.0 %	91.8 – 100.0%

The results demonstrate that the LIAISON® Toxo IgG II assay can be used with the LIAISON® XL Analyzer for the qualitative detection of IgG antibodies to *Toxoplasma gondii.*

C. CDC Panel Study:

The CDC Toxoplasma 1998 Human Serum Panel is comprised of 100 frozen blind specimens (70 Toxoplasma IgG true positive samples and 30 Toxoplasma IgG true negative samples .The panel was tested by LIAISON® Toxo IgG II assay at.

The results were submitted to the CDC (Reference Immunodiagnostic Lab, Biology and Diagnostic Branch Division of Parasitic Diseases) for data analysis. As communicated by the CDC, the LIAISON® Toxo IgG II assay correctly detected the 70 Toxoplasma IgG true positive samples (100% Sensitivity) and the 30 Toxoplasma IgG true negative samples (100% Specificity).

D. Prevalence:

The observed prevalence of the LIAISON® Toxo IgG II assay was calculated for the prospective populations consisting of the 804 samples from patients sent to the lab for *Toxoplasma gondii testing* and 202 pregnant women.

The prevalence may vary depending upon geographical location, age, gender, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

The observed prevalence of LIAISON® Toxo IgG II assay for the US population is 10.3%, the European population had a prevalence of 57.0% and pregnant women a prevalence of 5.9%.

PRECISION/REPRODUCIBILITY:

20 Day Study

Assay precision was evaluated according to CLSI EP5-A2. Six serum samples containing concentrations of analyte prepared to span the range of the assay and the LIAISON® Control Toxo IgG II (positive and negative) were assayed in duplicate in two runs per day over 20 operating days.

The following repeatability results were obtained from the samples tested internally at DiaSorin Inc. in one kit lot.

Repeatability

Sample ID	Sample N	Mean IU/mL	Within-Run		Within-Day		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Control*	80	<3.0	90.36*	5.6%*	89.13*	5.5%*	155.58*	9.6%*	200.8*	12.4%*
Pos Control	80	22.8	1.19	5.2%	0.68	3.0%	0.48	2.1%	1.45	6.4%
Sample #1*	80	<3.0	151.7*	6.3%*	48.72*	2.0%*	262.18*	10.9%*	306.8*	12.8%*
Sample #2	80	7.5	0.53	7.2%	0.54	7.2%	0.00	0.0%	0.75	10.0%
Sample #3	80	15.8	0.85	5.4%	0.58	3.7%	0.41	2.6%	1.11	7.0%
Sample #4	80	13.2	0.76	5.8%	0.82	6.2%	0.14	1.1%	1.13	8.5%
Sample #5	80	27.0	1.13	4.2%	1.21	4.5%	0.70	2.6%	1.80	6.6%
Sample #6	80	76.9	4.35	5.7%	2.94	3.8%	3.16	4.1%	6.12	8.0%

* Dose and corresponding RLU's were below the reading range of the assay. Precision calculations are based on signal (RLU) for the two samples.

The following reproducibility results were obtained from the same six samples and the LIAISON® Control Toxo IgG II (positive and negative) tested at two external sites and at DiaSorin Inc. in two kit lots assayed in duplicate in two runs per day over 20 operating days.

Reproducibility

Sample ID	Sample N	Mean IU/mL	Within-Run		Within-Day		Between-Day		Between Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Control*	480	<3.00	100.82*	6.4%*	87.89*	5.5%*	147.49	9.3%*	208.12*	13.1%*	320.20*	20.2%*
Pos Control	480	22.8	1.4	6.1%	0.74	3.3%	1.6	7.0%	0.7	3.1%	2.69	11.8%
Sample #1*	480	<3.00	136.38*	5.5%*	94.22*	3.8%*	215.71*	8.7%*	375.14*	15.2%*	603.16*	24.4%*
Sample #2	480	7.4	0.48	6.5%	0.33	4.5%	0.42	5.8%	0.21	2.8%	0.88	12.0%
Sample #3	480	15.3	0.79	5.2%	0.61	4.0%	0.8	5.2%	0.38	2.5%	1.72	11.2%
Sample #4	480	13.6	0.68	5.0%	0.6	4.4%	0.89	6.6%	0.44	3.2%	1.43	10.5%
Sample #5	480	26.9	1.23	4.6%	1.12	4.2%	1.43	5.3%	0.92	3.4%	2.81	10.5%
Sample #6	480	77.3	3.92	5.1%	4.42	5.7%	5.95	7.7%	2.77	3.6%	9.44	12.2%

* Dose and corresponding RLUs were below the reading range of the assay. Precision calculations are based on signal (RLU) for the two samples.

CONCLUSION:

The material submitted in this premarket notification is complete and supports a substantial equivalence decision. The labeling is sufficient and it satisfies the requirements of 21CFR 809.10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

DiaSorin Inc.
C/O Kelly Sauer, Regulatory Affairs Specialist
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285

Re: K132234
Trade/Device Name: LIAISON Toxo IgG II, LIAISON Control Toxo IgG II
Regulation Number: 21 CFR 866.3780
Regulation Name: *Toxoplasma gondii*, Serological Reagent
Regulatory Class: Class II
Product Code: LGD
Dated: July 11, 2013
Received: July 18, 2013

Dear Ms. Sauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132234

Device Name: LIAISON® Toxo IgG II
LIAISON® Control Toxo IgG II

Indications For Use: The LIAISON® Toxo IgG II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the qualitative determination of specific IgG antibodies to *Toxoplasma gondii* in human serum. The results of this assay can be used as an aid in the assessment of the patient's serological status to infection with *Toxoplasma gondii* and in the determination of immune status of individuals including pregnant women. This assay has not been cleared/approved by the FDA for blood/plasma donor screening.
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The LIAISON® Control Toxo IgG II (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Toxo IgG II assay on the LIAISON® XL Analyzer.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Ribhi Shawar -S